

SUBSTITUTE FORM PTO-1449  
(MODIFIED)

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.  
06275/034001

SERIAL NO.

08/601,005

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT  
(Use several sheets if necessary)

APPLICANT  
Kjell Bäckström et al.

FILING DATE  
March 1, 1996

GROUP 1615

(37 CFR 1.98(b))

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
<u>7.0</u>	AA	5 2 2 5 1 8 3	7/6/93	Purewal et al.	424	45	
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
<u>2.0</u>	AL	WO 91/11495	8/8/91	<del>PCT</del> WO				X
<u>2.1</u>	AM	O 518 600 A1	12/16/92	European Europe				
	AN							
	AO							
	AP							

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

	AQ							
	AR							
	AS							

EXAMINER

BAAW

DATE CONSIDERED

9/22/98

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EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE		
<div style="font-size: 2em;">P.13</div>	AA	3 0 1 4 8 4 4	12/26/61	Thiel et al.	167	82			
	AB	3 6 3 2 7 4 3	01/04/72	Geller et al.	424	45			
	AC	4 2 3 2 0 0 2	11/04/80	Nogrady	424	45			
	AD	4 5 4 8 9 2 2	10/22/85	Carey et al.	514	4			
	AE	4 6 1 3 5 0 0	09/23/86	Suzuki et al.	429	85			
	AF	4 6 9 0 9 5 2	09/01/87	Kagatani et al.	514	808			
	AG	4 7 4 6 5 0 8	05/24/88	Carey et al.	424	88			
	AH	4 7 8 8 2 2 1	11/29/88	Kagatani et al.	514	808			
	AI	4 7 9 4 0 0 0	12/27/88	Ecanow	424	457			
	AJ	4 8 4 7 2 9 8	07/11/89	Alexander et al.	514	565			
<div style="font-size: 2em;">P.13</div>	AK	4 8 4 9 4 0 5	07/18/89	Ecanow	514	3			
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							YES	NO	
	<div style="font-size: 2em;">P.13</div>	AL	837,465	15 JUN 60	GB	_____	_____		
		AM	WO 92/08446	29 MAY 92	<del>PCT</del> WO	_____	_____		
		AN	WO 91/04011	04 APR 91	<del>PCT</del> WO	_____	_____		
		AO	0 499 344 A2	27 NOV 89	<del>EP</del> Europe	_____	_____		
		AP	WO 91/16038	31 OCT 91	<del>PCT</del> WO	_____	_____		
		AQ	WO 91/14422	03 OCT 91	<del>PCT</del> WO	_____	_____		
AR		26 20 446.6	08 MAY 76	Germany	_____	_____			
AS		0 200 383	07 APR 86	<del>EP</del> Europe	_____	_____			
AT		0 360 340	18 SEP 89	<del>EP</del> Europe	_____	_____			
<div style="font-size: 2em;">P.13</div>		AU	8007820-7	17 NOV 86	Sweden	_____	_____		
EXAMINER BAWA				DATE CONSIDERED 9/22/98					
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2-13	BA	4 8 9 5 7 1 9	01/23/90	Radhakrishnan et al.	424	45		
	BB	4 9 0 0 7 3 0	02/13/90	Miyauchi	514	12		
	BC	4 9 5 9 3 5 8	09/28/88	Carey et al.	514	171		
	BD	4 9 6 3 3 6 7	10/16/90	Ecanow	424	485		
	BE	4 9 9 4 4 3 9	02/19/91	Longenecker et al.	514	3		
	BF	5 0 0 6 3 4 3	04/09/91	Benson et al.	424	450		
	BG	5 0 1 1 6 7 8	04/30/91	Wang et al.	424	45		
	BH	5 1 1 8 4 9 4	06/02/92	Schultz et al.	424	45		
	BI	5 1 2 2 3 7 6	06/16/92	Aliverti et al.	424	405		
	BJ	5 1 7 9 0 7 9	01/12/93	Hansen et al.	514	4		
2-13	BK	5 2 0 0 3 9 3	04/06/93	Weiner	514	3		
FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION								
		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
2-17	BL	1 527 605	04 OCT 78	<del>GB</del> Britain				
	BM	0 272 097	15 DEC 87	<del>EP</del> Europe				
	BN	<del>WO</del> 88/09163	01 DEC 88	<del>PCT</del> WO				
	BO	0 225 189	28 NOV 86	<del>EP</del> Europe				
	BP	WO 94/07514	14 APR 94	<del>PCT</del> WO				
	BQ	261 096 A1	20 MAY 83	Germany				
	BR	<del>WO</del> 90/07333	12 JUL 90	<del>PCT</del> WO				
	BS	0 055 041	03 DEC 81	<del>EP</del> Europe				
	BT	1 208 036	19 NOV 63	Germany				
2-17	BU	26 20 483	23 DEC 76	Germany				
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EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
P-13	CA	5 2 0 2 1 2 9	04/13/93	Samejima et al.	424	489		
	CB	5 2 8 4 6 5 6	02/08/94	Platz et al.	424	435		
	CC	5 3 0 6 4 8 3	04/26/94	Mautone	424	45		
	CD	5 3 4 8 7 3 0	09/20/94	Greenleaf et al.	424	45		
	CE	5 3 5 4 5 6 2	10/11/94	Platz et al.	424	489		
	CF	5 3 6 4 8 3 8	11/15/94	Rubsamen	514	3		
	CG	5 5 0 6 2 0 3	04/09/96	Backstrom et al.	514	4		
	CH	5 5 1 4 6 7 0	05/07/96	Friedman et al.	514	2		
P-13	CI	5 5 1 8 9 9 8	05/21/96	Backstrom et al.	514	3		
	CJ							
	CK							
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							YES	NO
P-13	CL	76 36431	03 DEC 76	France				
	CM	0 130 550	27 JUN 84	<del>EE</del> Europe				
	CN	0 133 252	19 JUL 84	<del>EP</del> Europe				
	CO	WO 91/11495	08 AUG 91	<del>PCT</del> WO				
	CP	0 518 600 A1	08 JUN 92	<del>EP</del> Europe				
	CQ	9400371-2	04 FEB 94	Sweden				
P-13	CR	9302198-8	16 MAY 94	Sweden				
	CS							
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7.13	DA	Allenby et al., "The absorption of Insulin Across the Respiratory Tract of the Guinea-Pig" The Aerosol Society, Fourth Annual Conference, University of Surrey, Apr. 9-11, 1990.
	DB	Aungst et al., "Comparison of the effects of various transmucosal absorption promoters of buccal insulin delivery" Int. J. Pharm. (Netherlands) 53(3):227-235, 1989. (abstract)
	DC	Bjork, "Starch Microspheres as a Nasal Delivery System for Drugs" ACTA Universitatis Upsaliensis 103, 1993.
	DD	Bjork et al., "Degradable starch microspheres as a nasal delivery system for insulin" Int. J. Pharm 47: 233-238, 1988.
	DE	Chandler et al., "Nasal absorption in rats. II Effect of enhancers on insulin absorption and nasal histology" Int. J. Pharm 76:61-70, 1991.
	DF	Cutie et al., "The Role of Dispersing Agents in Inhalation and Intranasal Aerosol Suspensions" Aerosol Age, pp. 52-54, 1985.
	DG	Damasy et al., "Intranasal Insulin" Diabetes Res. and Clin. Pract. 5:S163, 1988.
	DH	Edman et al., "Routes of Delivery: Case Studies: Nasal Delivery of Peptide Drugs" Advanced Drug Del. Rev. 8:165-177, 1992.
	DI	Gordon et al., "Nasal absorption of insulin: Enhancement by hydrophobic bile salts" Proc. Natl. Acad. Sci. 32:7419-7423, 1985.
	DJ	Hirai et al., "Effect of Surfactants on the Nasal Absorption of Insulin in Rats" Int. J. Pharm. 9:165-172, 1981.
	DK	Igawa et al., "Effect of Absorption Promoters in Intranasal Administration of Human Fibroblast Interferon.." Chem Pharm. Bull. 37:418-421, 1989.
7.13	DL	Komada et al., "Intratracheal Delivery of Peptide and Protein Agents: Absorption from Solution and Dry Powder by Rat Lung" J. Pharm. Sciences 83:863, 1994.

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2.13	EA	Lee et al., "Mucosal Penetration Enhancers for Facilitation of Peptide and Protein Drug Absorption" Crit. Rev. Therapeutic Drug Carrier Systems 8(2):91-192, 1991.
	EB	Lee et al., "Intranasal Bioavailability of Insulin Powder Formulations:..." J. Pharm. Sciences 80(8):725, 1991.
	EC	Mishima et al., "Studies on the Promoting Effects of Medium Chain Fatty Acid Salts on the Nasal Absorption..." J. Pharma. Dyn. 10:624-631, 1987.
	ED	Morita et al., "Effects of Various Absorption Promoters on Pulmonary Absorption of Drugs..." Biol. Pharm. Bull. 16:269-262, 1993.
	EE	Moses et al., "Insulin Administered Intranasally as an Insulin-Bile Salt Aerosol" Diabetes 32:1040, 1983.
	EF	Olanoff et al., "Method to Enhance Intranasal Peptide Delivery" American Chemical Society Symposium, Lee & Good, eds., New York, April 13-18, 1986.
	EG	Pontiroli et al., "Nasal administration of glucagon and human calcitonin to healthy subjects: a comparison of powders..." Eur. J. Clin. Pharmacol. 37:427-430, 1989.
	EH	SanGiovanni, "Just how practical is aerosolized nasal insulin" Spray Tech. & Marketing 2(1):16-19, 1992.
	EI	Schipper et al., "Nasal Insulin Delivery with Dimethyl-B-Cyclodextrin as an Absorption Enhancer in Rabbits..." Pharm. Res. 10:682, 1993.
	EJ	Touitou et al., "Targeted Enteral Delivery of Insulin to Rats" Int. J. Pharm. (AMST) 30:95-100, 1986.
	EK	Wearley, "Recent Progress in Protein and Peptide Delivery by Noninvasive Routes" Crit. Rev. in Therapeutic Drug Carrier Systems 8(4):331-394, 1991.
	EL	Wigley et al., "Insulin Across Respiratory Mucosae by Aerosol Delivery" Diabetes 20(8):552, 1971.
	EM	Yoshida et al., "Absorption of Insulin Delivered to Rabbit Trachea Using Aerosol Dosage Form" J. of Pharm. Sciences 68:670, 1979.
2.13	EN	Zinman, "The physiologic replacement of insulin" Medical Intelligence: Drug Therapy 321:363, 1989.

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